

Mesalamine

This sheet is about exposure to mesalamine in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is mesalamine?

Mesalamine is an anti-inflammatory (reduces inflammation or swelling) prescription medication. Mesalamine has been approved for use to treat ulcerative colitis, an inflammatory bowel disease (IBD). It belongs to a class of medications called 5-aminosalicylic acid (5-ASA). Another name for mesalamine is mesalazine. Some brand names for mesalamine that can be taken orally are Apriso®, Asacol®, Delzicol®, Lialda® and Pentasa®. Some brand names for mesalamine that can be taken rectally are Canasa®, Rowasa® and Pentasa®.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy. It is important to consider the benefits of controlling your IBD during pregnancy. Untreated IBD increases the risk for complications for both the person who is pregnant and the baby. For more information about IBD, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/

I take mesalamine. Can it make it harder for me to get pregnant?

Studies have not been done to see if mesalamine could make it harder to get pregnant.

Does taking mesalamine increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. One study among 146 people who used mesalamine in the first trimester did not find a higher chance of miscarriage.

Does taking mesalamine increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk.

One study reviewed medical records of over 2,000 infants who were reportedly exposed to mesalamine at some time during the first trimester of pregnancy. This study found a slightly higher chance of heart defects. Because many of the people in this study had also used other medications, it is hard to know if mesalamine, a combination of medications, the underlying disease, or other factors contributed to the reported slightly higher rate of heart defects.

There have been several other studies of pregnancies exposed to both oral and rectal mesalamine or a similar medication in the first trimester that have found no increased chance for birth defects.

Based on the available information, exposure to mesalamine is considered unlikely to significantly increase the chance for birth defects.

Does taking mesalamine increase the chance of other pregnancy related problems?

Mesalamine is not expected to increase the chance for pregnancy complications. There have been questions about a higher chance for preterm delivery (birth before 37 weeks) and stillbirth from earlier reports. However, more recent



data has not suggested an increased chance for these complications or for other pregnancy complications like low birthweight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

Does taking mesalamine in pregnancy affect future behavior or learning for the child? Studies have not been done to see if mesalamine can cause behavior or learning issues for the child.

Breastfeeding while taking mesalamine:

Mesalamine has been found in breastmilk in small amounts. Reports of diarrhea occurring in breastfed infants suggest that some infants may be sensitive to mesalamine in the breastmilk. There have also been reports of breastfed infants who did not have negative effects. When taking mesalamine while breastfeeding, the nursing infant should be watched closely for changes in bowel activity. Infants that are born preterm or are younger than one month of age have a stomach and intestines that are less mature than older babies. This might allow more medication to enter their blood stream. Be sure to talk to your healthcare provider about your breastfeeding questions.

If a male takes mesalamine, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

There have been some reports of males who had lower sperm count while taking mesalamine. This could make it harder to get a partner pregnant. Sperm counts returned to normal after stopping the medication. There are no studies looking at possible risks to a pregnancy when the father or sperm donor takes mesalamine. In general, exposures that fathers and sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

MotherToBaby is currently conducting a study looking at inflammatory bowel disease and the medications used to treat this condition in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972 or sign up at https://mothertobaby.org/join-study/.



Selected References:

- Allocca M, et al. 2018. Sexual and reproductive issues and inflammatory bowel disease: a neglected topic in men. Eur J Gastroenterol Hepatol. 30(3):316-322.
- Ban L et al. 2014. Limited risks of major congenital anomalies in children of mothers with IBD and effects of medications. Gastroenterology. 146 (1):76-84.
- Banerjee, A et al. 2019. Inflammatory Bowel Disease Therapies Adversely Affect Fertility in Men- A Systematic Review and Meta-analysis. Endocrine, metabolic & immune disorders drug targets, 19(7), 959–974.
- Chermesh I & Eliakim R. 2004. Mesalazine-induced reversible infertility in a young male. Dig Liver Dis 36:551-2.
- Watanabe, C. et al. 2020. Non-adherence to Medications in Pregnant Ulcerative Colitis Patients Contributes to Disease Flares and Adverse Pregnancy Outcomes. Digestive diseases and sciences, 10.1007/s10620-020-06221-6. Advance online publication.
- Diav-Citrin O, et al. 1998. The safety of mesalamine in human pregnancy: a prospective controlled cohort study. Gastroenterology; 114:23-28.
- Gaidos J. & Kane SV. 2020. Medication Adherence During Pregnancy in IBD: Compliance Avoids Complications. Digestive diseases and sciences, 10.1007/s10620-020-06271-w. Advance online publication.
- Hosseini-Carroll P, et al. 2015. Pregnancy and inflammatory bowel diseases: Current perspectives, risks and patient management. World J Gastrointest Pharmacol Ther. 6(4):156-171.
- Källén B. 2014. Maternal use of 5-aminosalicylates in early pregnancy and congenital malformation risk in the offspring. Scand J Gastroenterol; 49(4):442-8.
- Mahadevan U, Matro R. Care of the pregnant patient with inflammatory bowel disease. Obstet Gynecol. 2015;126:401-12.
- Maliszewska, AM, et al. 2017. Inflammatory bowel disease and pregnancy. Ginekologia Polska, 88(7), 398-403.
- Marteau P & Devaux CB. 1994. Mesalazine during pregnancy. Lancet 344(8938):1708-1709.
- Moskovitz DN, et al. 2004. The effect on the fetus of medications used to treat pregnant inflammatory bowel-disease patients. Am J Gastroenterol 99(4):656-661.
- Nelis GF. 1989. Diarrhoea due to 5-aminosalicylic acid in breastmilk. Lancet 1:383.
- Nielsen OH, et al. 2014. IBD medications during pregnancy and lactation. Nat Rev Gastroenterol Hepatol. 11(2):116-127.
- Norgård, B et al. 2003. Birth outcome in women exposed to 5-aminosalicylic acid during pregnancy: a Danish cohort study. Gut, 52(2), 243–247.
- Pervez, H, et al. 2019. The Impact of Inflammatory Bowel Disease on Pregnancy and the Fetus: A Literature Review. Cureus, 11(9), e5648.
- Shin T, et al. 2014. Inflammatory bowel disease in subfertile men and the effect of mesalazine on fertility. Syst Biol Reprod Med. 60(6); 373-376.
- Silverman DA, et al. 2005. Is mesalazine really safe for use in breastfeeding mothers? Gut 54: 170-1.
- Xu YL, et al. 2017. Inflammatory bowel disease in pregnancy: A report of 7 cases and review of the literature. Int J Clin Exp Med; 10:5525-32.